DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell WA 98041-3012

Telephone: 206-486-8788
Fax: 206-483-4996

d1698b

November 27, 1996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-06

David L. Boschma, Co-owner
Thomas Boschma, Co-owner
Boschma Dairy
13100 SW Hillsboro Highway
Hillsboro, Oregon 97123

WARNING LETTER

Dear Gentlemen:

An investigation at your dairy operation located at Hillsboro, Oregon, conducted on November 18, 1996, confirmed that you offered animals for sale for food in violation of Sections 402(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On March 20, 1996, you sold bull calves, identified with back tag numbers 92RK2201, 92RK2202, and 92RK2203, for slaughter as human food at [redacted] USDA analysis of tissue samples collected from these calves identified the presence of:

a) 15.0 ppm of neomycin in the kidney of calf 92RK2201,

b) 35.0 ppm of neomycin and 0.27 ppm oxytetracycline in the kidney of calf 92RK2202, and

c) 210.0 ppm of neomycin and 0.63 ppm oxytetracycline in the kidney of calf 92RK2203.

A tolerance of 0.25 ppm has been established for residues of neomycin in edible tissues of calves (Title 21, Code of Federal Regulations, Part 556.430 [21 CFR 556.430]). The presence of these drugs in edible tissues from these calves causes the food to be adulterated.

On April 3, 1996, you sold a bull calf, identified with back tag number 92RK0059, for slaughter as human food at [redacted] USDA analysis of tissue samples collected from the calf identified the presence of 10.0 ppm of neomycin in the kidney and 0.26 ppm of oxytetracycline in the liver. A tolerance of 0.25 ppm has been established for

residues of neomycin in edible tissues of calves (21 CFR 556.430) and 0.10 ppm has been established for residues of oxytetracycline in edible tissues of calves (21 CFR 556.500).

Our investigation found that you are adulterating the drug [redacted] that your dairy uses on calves within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

for John Vanderlaan

Roger L. Lowell
District Director